DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

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JUSTIFICATION
OFFICE OF AIDS RESEARCH

Budget Authority:

FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	Increase or Decrease
$2,004,428,000	**$2,243,365,000**	**$2,501,352,000**	**+257,987,000**

INTRODUCTION

The Exploding Global HIV/AIDS Pandemic

Group	People Newly Infected in 2000	People Living with HIV/AIDS	AIDS Deaths in 2000	Total AIDS Deaths
Adults *Women*	4.7 Million *2.2 Million*	34.7 Million *16.4 Million*	2.5 Million *1.3 Million*	17.5 Million *9.0 Million*
Children	600,000	1.4 Million	500,000	4.3 Million
Total ***Source: UNAIDS***	5.3 Million	36.1 Million	3.0 Million	21.8 Million

By every definition, AIDS is the great plague of the 20th century. HIV has infected more than 50 million people around the world. AIDS already has killed more than 21 million people, surpassing tuberculosis and malaria as the leading infectious cause of death worldwide, according to data released by the Joint United Nations Programme on HIV/AIDS (UNAIDS) in the "AIDS Epidemic Update: December 2000" and the World Health Report 2000 of the World Health Organization (WHO).

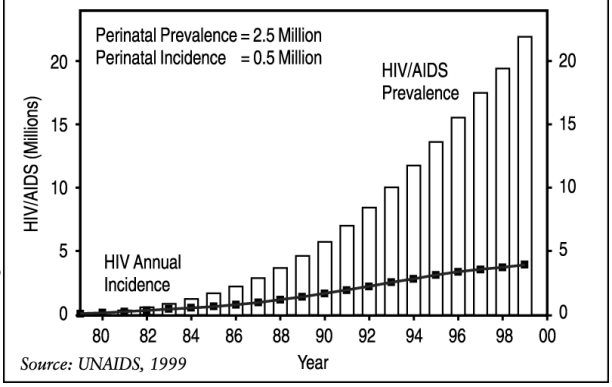
The seriousness of the crisis in Africa was dramatized in January 2000 when the United Nations Security Council highlighted the growing epidemic and declared that AIDS has become an issue of national security, representing a new kind of threat to political stability. It was the first time the Security Council placed a health issue on its agenda, and the first time a sitting U.S. Vice President addressed the Security Council.

If the global spread of HIV/AIDS continues unchecked, South and Southeast Asia, and perhaps China will follow the disastrous course of sub-Saharan Africa. Currently, there are an estimated 5.8 million HIV-infected people in South and Southeast Asia. In India alone, UNAIDS estimates that between 3 and 5 million of its nearly 1 billion population are infected, and the number of new infections is continuing to double every 14 months. Rapid increases also are occurring in Eastern Europe and Central Asia, and AIDS remains a serious threat in Latin America and the Caribbean. During the year 2000, more new HIV

infections will have been registered in the Russian Federation than in all previous years of the epidemic combined.

Recent data indicate that worldwide there are now almost equal numbers of men and women infected with HIV. In sub-Saharan African, UNAIDS/WHO estimated that more women than men were living with HIV/AIDS at the end of 1999: 12.2 million women and 10.1 million men between the ages of 15-49. Curbing the transmission of HIV from infected mother to infant is an especially compelling challenge in developing countries.

HIV Incidence and HIV/AIDS Prevalence, Sub-Saharan Africa, 1980–1999



Source: UNAIDS, 1999

The coexistence of other endemic diseases widely prevalent in developing countries, such as respiratory and gastrointestinal infections, complicate treatment and pose additional problems for medical personnel caring for HIV-infected individuals. Of particular note is the parallel epidemic of tuberculosis in the developing world. Attitudes, beliefs, and taboos surrounding sex, the status of women and children, and the source and etiology of AIDS can complicate attempts to control transmission and provide appropriate prevention and treatment.

The HIV/AIDS Epidemic in the United States

In the United States, the HIV/AIDS epidemic continues to evolve. Although the incidence of new AIDS cases has declined, attributed largely to expanded use of new antiretroviral therapies that prevent progression of HIV infection to AIDS, the decline in death rates observed in the late 1990s has leveled off. Further, according to the Centers for Disease Control and Prevention (CDC), the rate of new HIV infections has been constant at approximately 40,000 new cases each year since 1990, meaning that the overall epidemic is continuing to expand. In fact, HIV infection rates are continuing to climb in a number of subpopulation groups, such as women, racial and ethnic minorities, young homosexual men, individuals with addictive disorders, and people over 50 years of age. The recent appearance of multi-drug resistant strains of HIV present a serious public health concern. These data forebode an epidemic of even greater magnitude in the coming years.

AIDS disproportionately affects African Americans and Hispanics. They account for 45 percent and 20 percent, respectively, of all persons newly diagnosed with AIDS during 1998. CDC's HIV/AIDS Surveillance Report of June 1999 states that among women with AIDS, minorities account for 80 percent of cases; among men, minorities account for 61% of cases. Addressing these racial disparities is a high priority for the NIH.

Setting the AIDS Research Priorities

In response to this pandemic, NIH has developed a comprehensive biomedical and behavioral research program to better understand the basic biology of HIV, develop effective therapies to treat it, and design interventions to prevent new infections from occurring. It is the role of the Office of AIDS Research

(OAR) to plan and coordinate this research program sponsored by all 25 NIH Institutes and Centers. The changing demographics in the epidemic demand careful consideration in planning our research agenda, since different prevention and intervention strategies must be applied to each subepidemic.

OAR develops an annual comprehensive AIDS research plan and budget, based on the most compelling scientific priorities that will lead to better therapies and prevention for HIV infection and AIDS. Those priorities are determined through a unique and collaborative process involving the NIH institutes and non-government experts from academia and industry, with the full participation of AIDS community representatives. The plan is divided into five Scientific Areas of Emphasis and four Areas of Special Interest. *Scientific Areas of Emphasis* include: Natural History and Epidemiology; Etiology and Pathogenesis; Therapeutics; Vaccines; and Behavioral and Social Science. *Areas of Special Interest*, which cross-cut all of the scientific areas, include: Racial and Ethnic Minorities; International Research Priorities; Training, Infrastructure, and Capacity Building; and Information Dissemination. The Plan serves as the framework for developing the NIH AIDS budget, for determining the use of NIH AIDS-designated dollars, and for tracking and monitoring those expenditures. Highlights of the Plan are included in this budget request, and the entire plan can be found on the OAR Web site: **http://www.nih.gov/od/oar/.**

Overview of the AIDS Research Agenda

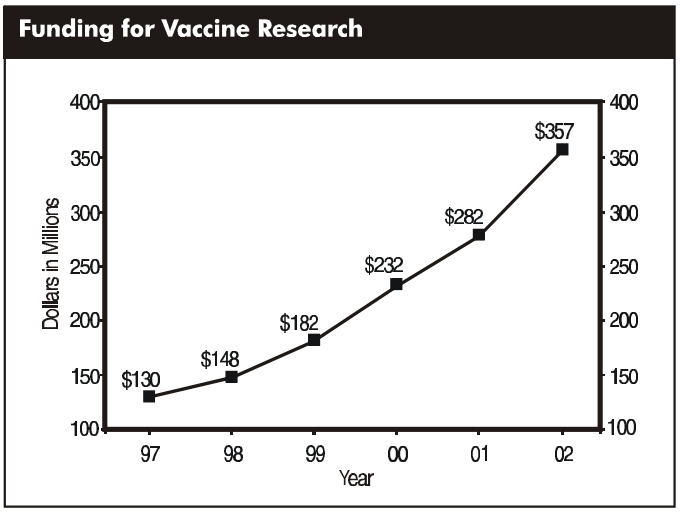
Four major themes frame the FY 2002 Research Plan: prevention research to reduce HIV transmission here in the United States and around the world; therapeutic research to treat those who are already infected; international research priorities, particularly to address needs in developing countries; and research targeting the disproportionate impact of AIDS on minority populations in the United States. All of these efforts require a strong foundation of basic science.

Prevention Research

The transmissible nature of HIV makes it radically different from non-transmissible diseases such as heart disease and cancer. The transmissibility of HIV--between individuals and across borders and populations--is what most defines the global pandemic and makes it imperative that the U.S. help address prevention and treatment needs worldwide. The transmissibility of the infection means that there is the potential for unlimited global spread. But it also means that, with the development of appropriate biomedical and behavioral interventions, there is the possibility for dramatic reductions in new infections--and ultimate control of the pandemic--in a way that will not be possible for noninfectious diseases.

NIH supports a comprehensive approach to HIV prevention research that includes contributions from the biomedical, behavioral, and social sciences. The OAR prevention science research agenda targets interventions to both infected and uninfected at-risk individuals to reduce HIV transmission. Our biomedical prevention research priorities include the development of topical microbicides, strategies to prevent perinatal transmission (including a better understanding of risk associated breast-feeding), and management of sexually transmitted diseases. NIH also supports behavioral research strategies, including prevention interventions related to drug and alcohol use and risky sexual behaviors. Efforts continue to identify the most appropriate intervention strategies for different populations and sub-epidemics in the U.S. and around the world. The OAR Prevention Science Working Group continues to provide advice about

HIV prevention research priorities.



Vaccine Research

A safe and effective HIV preventive vaccine is essential for the global control of the AIDS pandemic. NIH funding for HIV vaccine research increased by more than 170 percent between FY1997 and FY2002, resulting in the award of new grants to foster innovative research on HIV vaccines, including vaccine design and development, and the invigoration and reorganization of the NIH vaccine clinical trials effort. Construction of the new intramural Vaccine Research Center has been completed. In February 1999, NIH-supported investigators initiated the first AIDS vaccine trial in Africa. The AIDS Vaccine Research Committee, chaired by Nobel laureate Dr. David Baltimore, continues to provide critical advice on all aspects of the NIH AIDS vaccine development program. The changes implemented in this area over the past few years have enormous significance, not only for AIDS research but for other diseases as well, as progress made in the development of an AIDS vaccine will have implications for vaccines against other life-threatening illnesses.

Behavioral and Social Science Research

Studies have demonstrated that behavioral change can successfully prevent or reduce the spread of HIV infection in both domestic and international settings. Prevention programs resulting from such studies have altered sexual and drug-using behaviors and have reduced the risk of transmission in many communities and subgroups. NIH supports research to further our understanding of how to change the behaviors that lead to HIV transmission—including preventing their initiation—and how to maintain protective behaviors once they are adopted in all populations at risk. NIH also supports research on preventing and mitigating the psychosocial consequences of HIV/AIDS on individuals and communities.

Topical Microbicides Research

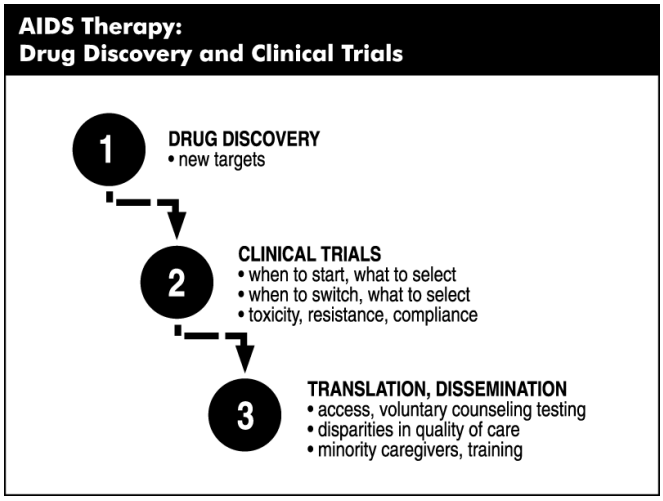
The vulnerability of women to acquiring HIV infection demands the development of effective and acceptable female-controlled chemical and physical barrier methods, such as topical microbicides, to reduce HIV transmission. To enhance and stimulate research in this area, the OAR co-sponsored the first international conference devoted to all aspects of microbicide research and development. The conference, Microbicides 2000, included more than 600 participants from 45 nations. NIH is supporting Phase I, Phase II, and Phase III trials of various topical microbicides. NIH also supports behavioral and social research on the acceptability and use of microbicides among different populations. Additional efforts are essential to accelerate microbicides research and to ensure a comprehensive program for screening, discovery, development, preclinical testing, and clinical evaluation of potential spermicidal and nonspermicidal topical agents and other barrier methods. To that end, OAR is preparing a strategic plan for microbicide research.

Mother-To-Child Transmission

In the United States, regimens of antiretroviral drugs resulting from NIH-supported research have dramatically reduced transmission from infected mother to infant. However, the complexity of administration and high cost and make this option impractical for much of the developing world. For example, NIH-supported clinical trials in Uganda recently demonstrated that a single dose of the non-nucleoside reverse transcriptase inhibitor nevirapine—given to women during labor and followed by a single dose administered to their newborns, at a total cost of approximately $4—reduced transmission by half, compared with a similar and considerably more costly short course of AZT. This advance can substantially lower the cost barrier that has kept many countries from adopting drug strategies that prevent perinatal HIV transmission. However, lack of health care infrastructure or access to other health care services may still affect the ability of developing countries to implement this regimen. Further research on this and other low-cost alternatives is included in this plan. Another key research issue is the need for better methods for the reduction of HIV transmission through breast-feeding.

Treatment Research

The development of therapeutics for HIV/AIDS has long been a focus of NIH. Today, many HIV-infected people are living with the benefits resulting from NIH-supported research in this area. The development of combination regimens including protease inhibitors has extended the length and quality of life for many HIV-infected individuals in the United States and Western Europe. Unfortunately, however, highly active antiretroviral therapy (HAART) has failed to eradicate HIV, and a growing proportion of patients receiving therapy experience treatment failure. Some patients find it difficult or impossible to comply with arduous treatment regimens, develop toxicities and side-effects, or cannot afford their high cost of approximately $15,000 per year. Others fail to obtain a satisfactory reduction in viral load even while adhering to treatment regimens. In addition, metabolic complications, including insulin resistance, and body composition changes such as deforming deposits of abdominal adipose tissue, have emerged in individuals who have been on long-term antiretroviral regimens. Finally, an increasing number of treatment failures are linked to the increasing emergence of drug-resistant HIV.



The need for simpler, less toxic, and cheaper drugs and drug regimens to treat HIV infection and its associated opportunistic infections (OIs), malignancies, and other complications, continues to be a high priority. This includes the discovery and development of the next generations of antiviral drugs directed against new cellular and viral targets. Clinical trials will help to better define when to begin and/or switch

drugs within a regimen as well as to identify regimens for treatment-experienced individuals who no longer respond to these anti-HIV drugs. Antiretroviral and OI prophylaxis regimens are becoming increasingly complex with respect to drug-drug interactions and adherence. Protease inhibitors, in particular, interact with each other and many other medications commonly used by HIV-infected individuals. Additional research is under way and planned to address these issues with the goal of minimizing viral replication and delaying disease progression, drug resistance, and development of manifestations such as metabolic complications and body composition changes.

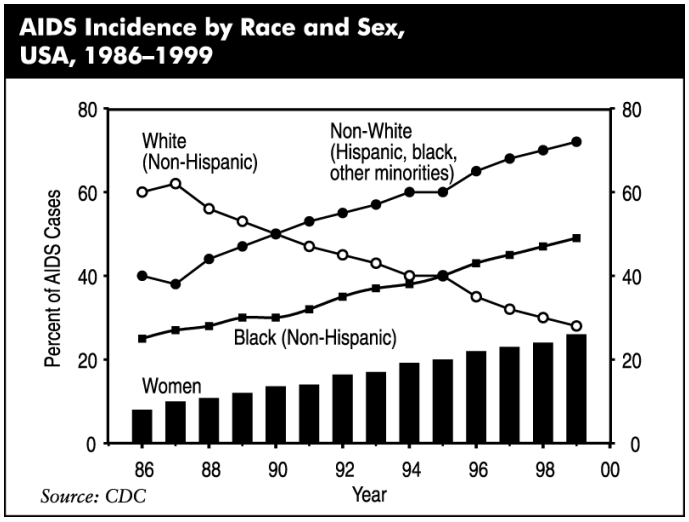
Basic Science

Of paramount importance in our fight against HIV/AIDS is maintaining a strong commitment to basic research. Tremendous progress has been made in understanding the fundamental steps in the life-cycle of HIV, the host-virus relationship and the clinical manifestations attending HIV infection and AIDS. Groundbreaking research on basic HIV biology and AIDS pathogenesis has revolutionized the design of drugs, the methodologies for diagnosis, and the monitoring for efficacy of antiviral therapies. In spite of these achievements, we still do not have a clear understanding of major aspects of the virus interaction with the infected individual, the nature of the immune response to the virus, how the virus establishes infection and spreads throughout the body, and its mechanisms of pathogenesis. This basic knowledge is critical for our efforts to prevent and control HIV infection and disease progression. In addition, basic behavioral and social science studies are also needed to provide further information on risk factors and behaviors, and the identification of populations at risk. These areas of investigation, driven by investigators-initiated research, have provided the constantly advancing knowledge base that permits the development of new applications for the prevention and treatment of HIV/AIDS. Thus, a substantial portion of NIH AIDS-related research will continue to be devoted to fundamental biomedical, behavioral, and social science research.

International Research Priorities

To address the increasing urgency of the global AIDS pandemic, the OAR has established a new initiative and strategic plan for global research on HIV/AIDS aimed at slowing the disaster and reversing its destruction of communities, economies and nations worldwide. The Global AIDS Research Initiative and Strategic Plan reaffirms NIH's long-standing commitment to international AIDS research and will significantly increase research efforts in the coming year to benefit resource- and infrastructure-poor nations. NIH supports a growing portfolio of research conducted in collaboration with investigators in developing countries. Results of this research benefit the people in the country where the research is conducted as well as people affected by HIV/AIDS worldwide. NIH collaborates with UNAIDS, host country governments, and in-country scientists for vaccine development and in preparations for efficacy trials. NIH-sponsored programs target studies on factors related to HIV transmission and the pathogenic mechanisms associated with HIV disease progression through studies in Africa, Asia, and Latin America. It is critical to the success of international studies that foreign scientists be full and equal partners in the design and conduct of collaborative studies and that they have full responsibility for the conduct of studies in-country. To that end, NIH supports international training programs and initiatives that help to build infrastructure and laboratory capacity in developing countries where the research is conducted.

Racial and Ethnic Minorities



Research to address the disproportionate impact of the HIV/AIDS epidemic on U.S. racial and ethnic minority communities continues to be a high priority. OAR has established the Ad Hoc Working Group on Minority Research to advise us on the scientific priorities in this critical research area, which are reflected in this plan. We are directing increased resources toward new interventions that will have the greatest impact on these groups. These include interventions that address the co-occurrence of other STDs, hepatitis, drug abuse, and mental illness; and interventions that consider the role of culture, family, and other social factors in the transmission and prevention of these disorders in minority communities. NIH is making significant investments to improve research infrastructure and training opportunities for minorities, and we will continue to assure the participation of minority subjects in AIDS clinical trials as well as in natural history, epidemiologic, and prevention studies. In response to the Congressional Black Caucus initiative, the OAR has provided additional funds to projects aimed at: increasing the number of minority investigators conducting behavioral and clinical research; targeting the links between substance abuse, sexual behaviors and HIV infection; increasing outreach education programs targeting minority physicians and at-risk populations; and expanding our portfolio of population-based research. One of these projects was a Training and Career Development Workshop for racial and ethnic minority investigators. This workshop provided minority investigators with an opportunity to learn about available NIH funding mechanisms and to meet and network with senior minority investigators who receive significant levels of NIH funding.

AIDS Research Benefits Other Diseases

AIDS research is unraveling the mysteries surrounding many other infectious, malignant, neurologic, autoimmune and metabolic diseases. AIDS research has provided an entirely new paradigm for drug design and development to treat viral infections. For example, the drug known as 3TC, developed to treat AIDS, is now the most effective therapy for chronic hepatitis B infection. Drugs developed to prevent and treat AIDS-associated opportunistic infections also provide benefit to patients undergoing cancer chemotherapy or receiving anti-transplant rejection therapy. AIDS is also providing new understanding of the relationship between viruses and cancer.

SCIENCE ADVANCES AND NEW INITIATIVES

FY 2002 Plan for HIV-Related Research

This budget request is framed on the scientific priorities and objectives of the FY 2002 strategic plan. The key priorities for each research area and directions for future research contained in the plan are summarized below.

THERAPEUTICS

Research Priorities of the FY 2002 Plan

- Advance the discovery of new anti-HIV agents by facilitating research on new or understudied viral and host targets, and develop new models and methodologies for predicting the effects and efficacy of anti-HIV agents in humans.
- Develop and evaluate therapeutic approaches that will enhance, restore, or maintain the immune systems of HIV-infected individuals.
- Conduct clinical studies to identify more effective, less toxic, and easier-to-take drug regimens; determine when antiretroviral regimens should be initiated or switched for optimal patient care; and evaluate the long-term effects of antiretroviral therapy.
- Develop and test safe, effective, and feasible microbicides and other chemical and physical barriers to halt sexual transmission of HIV and sexually transmitted diseases (STDs).

Ground breaking research in basic biology has led to a revolution in drug design and diagnostic methodologies that are benefitting the fight not only against AIDS, but also against other diseases. This basic research has been the foundation for the development of medications that are extending the length and quality of life for many HIV-infected individuals. Most important of these advances has been the demonstration that multidrug combinations of antiretroviral agents significantly reduce the viral load in many patients to undetectable levels. This reduction in HIV is accompanied by increases in CD4 cell counts and, in many cases, the amelioration of HIV-related symptoms.

However, there are limitations to these therapies, including the persistence of HIV reservoirs and ongoing viral replication; toxicities and side effects, including metabolic complications and body composition transformations; mineral and bone loss; rigid dosing regimens; and high cost.
Further research is needed to identify therapeutic regimens that are less toxic, limit development of drug resistance, enter viral reservoirs to inhibit viral replication, permit easier adherence, and are more readily accessible. Further studies also are needed to evaluate delayed and long-term effects of these antiretroviral drugs.

The scientific agenda for this area of research is focused on answering the following questions:

- When should antiretroviral (HAART) therapies be initiated?

- How long can successful therapies maintain decreased viral loads, increased CD4 counts, and improved clinical outcomes?
- When should antiretroviral therapies be changed?
- What is the basis for the emergence of drug resistance, and how can it be prevented?
- What are the long-term clinical efficacy and tolerability associated with HAART?
- Can treatment strategies be developed for patients who no longer respond to current regimens?
- Can immune-restorative/immune-enhancing approaches rebuild the immune system, so that disease progression is delayed?
- Can treatment strategies be developed to eliminate HIV, so that it is not transmitted from an infected individual to others?

Recent advances in therapeutics research underscore the importance of continued and further collaboration of Government- and industry-sponsored drug development research and clinical trials with the common goal of developing therapeutic regimens that slow disease progression, extend life spans, and improve the quality of life for HIV-infected individuals.

NIH-sponsored programs provide resources for conducting preclinical testing of potential compounds against HIV infection and its sequelae. Further development of ex vivo and animal models to evaluate agents for their potential pharmacologic properties and toxic effects is important to accelerate the identification of new and better compounds for entry into clinical trials.

One of the highest priorities of NIH-sponsored research is the clinical evaluation of potential agents against HIV infection and its associated OIs and malignancies. Current therapeutic regimens are extremely complex; patients may experience drug-drug interactions as well as difficulties in adhering to rigid dosing schedules that can lead to drug-resistant strains.
HIV continues to replicate at low levels in various reservoirs or sanctuary sites, making it possible for drug-resistant strains to emerge. Recent research has demonstrated the existence of a reservoir of latently infected cells that persists for prolonged periods of time, even in patients whose plasma viral load decreases to undetectable levels. These cells are infected during the acute phase of primary infection and form a source for HIV replication following drug withdrawal or HIV gene activation. Research is needed to develop new drugs that are safe and effective, can penetrate all compartments of the body, can be easily adhered to, and possess few toxic or complicating side effects, such as metabolic complications and body composition alterations, which have been associated with protease inhibitors. Given the limits of current antiretroviral therapies, immune-based and immune restorative therapies are needed, especially for individuals at more advanced stages of disease and immune depletion.

ETIOLOGY AND PATHOGENESIS

Research Priorities of the FY 2002 Plan

- Facilitate the translation of new insights into HIV biology to develop novel interventions for the prevention and treatment of HIV infection.
- Elucidate the biologic determinants of HIV transmission between individuals and define the mechanisms by which host factors, viral factors, and cofactors may influence the process of virus transmission.
- Investigate the mechanism of persistence of HIV infection; define the direct and indirect mechanisms that lead to T-cell depletion following HIV infection and the factors that determine numerical and functional reconstruction of T-cell populations in response to therapy.
- Advance the understanding of the mechanisms responsible for the toxicities and long-term complications of antiretroviral therapy and the factors that underlie changes in the causes of morbidity and mortality in an era of increasingly effective therapies.

Basic research is critical to provide a better understanding of how HIV infection is established and what causes the profound immune deficiency and terrible complications that accompany this infection. This research plays a vital role in the development of interventions to block transmission and slow disease progression in all populations at risk. The research programs of the NIH will continue to support a broad and vigorous program to study life processes, using cutting edge methods. This area of investigation, driven by investigator-initiated research, has provided the constantly advancing knowledge base that permits the development of new applications for the prevention and treatment of disease.

What role do the specific products of HIV (the viral genes and their protein products) play in the viral life cycle in individual cells and within the body of infected individuals? How is HIV transmitted between cells and between individuals? What contribution does the immune system make to controlling the infection and to the disease process? What mechanisms are involved in cell injury and death in the immune, nervous, and other systems that HIV afflicts? What host factors and cofactors influence the course and outcome of HIV infection? What is the relationship of HIV infection to the associated malignancies, OIs, neurological impairments, and metabolic disturbances that characterize AIDS? These outstanding questions define the central contemporary issues encompassed within the area of etiology and pathogenesis research.

The dramatic success of effective antiretroviral therapies in reducing plasma viremia to undetectable levels had raised the intriguing possibility that prolonged therapy might lead to virus eradication. However, recent data have indicated that the virus can persist in the body of HIV-infected patients for almost a lifetime. HIV can persist in a latent reservoir of resting memory CD4 T cells that is established very early after infection and by continuously replicating, albeit at very low levels, even in the presence of antiretroviral therapies able to drive viral load below the limits of detection. A better understanding of the different mechanisms of viral persistence is needed to understand the reasons for drug failure, to design rational

approaches for virus eradication, and to better assess the impact of persistence on HIV transmission and its implications for HIV prevention.

Understanding the normal development and functioning of the human immune system is crucial to our ability to understand the effects of HIV on the immune system and the pathogenesis of AIDS. This understanding also holds the key to designing rational immune reconstitution approaches in persons undergoing antiretroviral treatment and identifying the characteristics of the immune response that are needed for a protective vaccine.

The basic science underlying HIV etiology and pathogenesis research is generally gender neutral. Basic mechanisms of viral replication and pathogenesis are not expected to differ in women and men. However, there are differences in the way HIV infection is transmitted and how the disease is manifested in women and men. Studies have been designed to elucidate the pathogenic mechanisms more commonly observed in women, children, and adolescents infected with HIV. Transmission of HIV-1 from a mother to her infant may occur in utero through transplacental passage of virus, during delivery, or postnatally through breast-feeding. Many basic issues associated with maternal-fetal transmission remain unclear and are actively under investigation.

To ensure the continued growth of a powerful arsenal against HIV, it is imperative that scientists continue to study HIV pathogenesis and identify new targets for the design of drugs and vaccines. Design and development of new drugs are based on the study of the fundamental structural properties of the relevant viral targets. Efforts to develop effective therapies to treat HIV infection and its associated illnesses are providing a critical proving ground for the concept of rational drug design and for the refinement and advancement of its methods.

AIDS is associated with a broad spectrum of cancers and tumors. Because HIV causes immunosuppression and most AIDS-associated malignancies are strongly associated with viruses, HIV infection provides a unique model to study the interplay of viruses, a dysfunctional immune system, and the development of cancers. Elucidation of the interactive factors involved in the pathogenesis of AIDS-associated malignancies will possibly translate in the identification of new targets for prevention and treatment.

HIV infection results in progressive damage of the immune systems of infected individuals and makes them susceptible to a diverse collection of bacteria, viruses, fungi, and protozoa that represent the major causes of suffering and death for HIV-infected individuals. Opportunistic infections can affect virtually every tissue and organ system in the body, resulting in severe functional compromise. NIH currently supports a comprehensive portfolio of basic research on the pathogenesis of AIDS-associated OIs.

NATURAL HISTORY AND EPIDEMIOLOGY

Research Priorities of the FY 2002 Plan

- Determine the mechanisms and develop interventions to prevent postpartum transmission (i.e., resulting from breast-feeding).
- Evaluate the net impact of antiretroviral therapies on HIV transmission.
- Determine the biological characteristics, sociocultural factors, and health services issues that alter the dynamics of transmission and disease progression in men and women, as well as in the various racial and ethnic groups.
- Characterize the relative importance of alcohol and drug use in the acquisition and subsequent transmission of HIV in order to identify and apply appropriate alcohol and drug use interventions as public health measures.

Epidemiologic research continues to show the demographics of HIV infection and AIDS in the United States shifting from an illness primarily affecting homosexual and bisexual men to an epidemic with increasing and disproportionate rates of infection in minorities, women, adolescents, drug users, and heterosexuals. This shift has placed urban, minority and disenfranchised communities at the intersection of several overlapping epidemics: AIDS, sexually transmitted diseases (STDs), tuberculosis (TB), and drug use. NIH will continue to support research to examine topics in HIV transmission, HIV/AIDS disease progression (including the occurrence of OIs), malignancies, metabolic complications, neurological and behavioral dysfunctions, and the development of other HIV/AIDS-related conditions. Further studies are needed to investigate the effects of viral, host, and other factors on transmission and disease progression. Results from these studies will provide new directions and improvements in HIV/AIDS prevention and care.

International epidemiologic studies supported by NIH contribute significantly to the understanding of the cellular and molecular mechanisms of HIV transmission, the progression of HIV-related disease, and the risk factors associated with HIV infection. These studies also contribute to the development of new biomedical and preventive behavioral intervention strategies.

The effects of the new antiretroviral therapies on HIV transmission are not completely understood. A few studies suggest that individuals on antiretroviral therapy may be less likely to transmit HIV infection because they have lower viral loads after treatment. The result of this phenomenon may be a decrease in the rates of transmission and HIV incidence. However, the net effect of the perception that individuals on antiretrovirals may be less likely to transmit HIV infection may be that more people are taking greater sexual risks. Thus, the paradoxical consequence of the lower viral loads that result from antiretroviral therapies may be higher rates of HIV transmission and infection. Because biological, pharmacological, psychological, and behavioral factors all potentially influence the impact of antiretroviral therapies on HIV transmission, there is a need to evaluate the specific contributions of these factors and their net impact on

HIV transmission.

Another area of primary prevention research focuses on developing new or improved means of reducing perinatal transmission in the United States and worldwide, with particular emphasis on methods appropriate to the developing world. NIH is supporting studies to better understand the timing, mechanisms, and risk factors of perinatal transmission; whether specific strains are more likely transmitted; the potential benefit of Caesarean section; and development of newer therapeutic regimens and immunotherapy. The elimination of perinatal transmission in our nation and the world is a goal that is being vigorously pursued.

Ethnic and racially diverse cohorts of HIV-infected individuals and HIV-uninfected individuals at risk of infection are followed in clinical epidemiology studies at domestic and international sites. By maintaining this diversity, data obtained from such studies will have validity for all communities impacted by HIV infection.

Like many other diseases in the United States, HIV/AIDS has become concentrated in urban, disenfranchised communities of low socioeconomic status, as well as in certain racial and ethnic minority groups (i.e., African Americans and Hispanics). A determination of the biological characteristics, sociocultural factors, and health services issues that contribute to the differential dynamics of HIV transmission and disease progression in men, women, and in different race/ethnicity groups is needed for developing appropriate prevention and treatment strategies across at-risk populations in domestic and international settings.

BEHAVIORAL AND SOCIAL SCIENCES (including Non-Vaccine Prevention)

Research Priorities of the FY 2002 Plan

- Monitor, understand, and address the disparate risks and impact of HIV infection, as well as the disparate access to, and utilization and quality of, prevention and care services according to race/ethnicity, gender, age and socioeconomic status.
- Identify and address psychological, social, cultural, and ethical issues related to the initiation, maintenance, sustainability, replicability, and durability of effective HIV prevention, testing, counseling, and care efforts within communities over time, including efforts targeting HIV-infected individuals.
- Investigate the social and environmental factors that contribute to HIV infection, behaviors after infection, and co-occurring conditions (e.g., substance use, mental illness, homelessness, hepatitis, STDs, tuberculosis [TB]), including the causes and implications of stigma.
- Investigate both the facilitators and the barriers to policy decisions and public health implementation informed by behavioral and social science findings, including the development of interventions targeting the attitudes, capacities, and resources of HIV service providers and selected institutional settings (e.g., prisons, schools).

The primary goal of NIH-sponsored AIDS-related behavioral and social science research is to discover how to change the behaviors that lead to HIV transmission—including preventing their initiation—and how to maintain protective behaviors once they are adopted. An additional goal is to reduce the negative impact of HIV on individuals with HIV infection, their families, the health care system, and society. Three themes cross-cut, and are implicit in, priority areas in AIDS-related behavioral and social science: addressing ethical considerations in the conduct of research; further developing appropriate research methods; and investigating issues in both domestic and international settings, as appropriate.

NIH sponsors research related to the following: developing, implementing, and evaluating behavioral and social interventions to reduce HIV transmission in a range of populations and settings; strengthening our understanding of the determinants, trends, and processes of HIV-related risk behaviors and the consequences of HIV infection; developing and evaluating behavioral strategies for preventing or ameliorating the negative physical, psychological, and social consequences of HIV infection; and improving the research methodologies employed in behavioral and social science research.

It is imperative to better understand the behaviors that influence HIV transmission and protection and to develop and implement prevention programs based on this understanding. Scientifically-based interventions have been demonstrated to alter sexual and drug using behavior and reduce the risk of transmission among a number of population groups, but we are still far from realizing the full potential of such prevention research on a global scale. A more refined understanding of social and cultural factors that contribute to HIV risk or protection, particularly in minority communities, will have an enormous influence on the successful implementation of a broader range of preventive or therapeutic measures. Drug

users and their sex partners are the fastest growing segment of AIDS cases in the United States and in many other countries. High priority is being given to research to understand the phenomenon of addiction itself, as well as the complex interaction of alcohol use, drug use, and poor impulse control, and to develop effective interventions from that knowledge base.

The development of new and more effective drug therapies—in particular combination therapies—for combating HIV infection has raised a host of behavioral questions that have significant implications for HIV prevention and treatment. With combination therapies, the number of drugs and frequency of dosing require strict adherence to regimens that may be difficult for many people to achieve. Lack of complete adherence may result in the development of drug-resistant strains of HIV, which could have devastating implications for our ability to stem transmission and treat HIV-infected individuals. In addition, as HIV-infected individuals experience improved health and a decline in detectable virus in their body as a result of taking the new combination therapies, they may believe that they are less infectious and may lapse into unsafe sexual and drug-using behaviors. This could have the effect of increasing HIV transmission, if the virus is still viable at undetectable levels. These issues highlight the importance of research on how best to ensure adherence to both pharmacological and behavioral
HIV-related interventions.

VACCINES

Research Priorities of the FY 2002 Plan

- Continue to expand core programs in HIV/AIDS vaccine research and development to ensure that the research pipeline for vaccine research and development is robust.
- Conduct clinical trials of promising vaccine candidates in both domestic and international settings: conduct Phase I and II trials of products, moving new concepts and products into human testing as rapidly as possible; and enable the conduct of efficacy trials with sufficient lab support to define correlates of immunity.
- Expand immunological assessment of vaccines: ensure that standardized assays are developed that are precise, sensitive, and practical; develop and provide resources and appropriate reagents for these assays; strengthen the immunological assessment of clinical vaccine trials; study the immune responses in neonates and infants to assure development of appropriate vaccine products for breast-feeding populations.
- Invest in the development of critical vaccine research capabilities, information dissemination, and education to conduct vaccine trials in populations with a high incidence of HIV infection, in both the United States (including minority populations, adolescents, and women) and in international settings.

Vaccine research remains one of the highest research priorities. The toll of the epidemic in poorer countries where therapeutic and prevention interventions are unavailable or unaffordable, as well as in

industrialized parts of the world, dictates the important emphasis on vaccine development. A safe and effective vaccine is the critical missing element in our armamentarium for the prevention of HIV and ultimate control of the pandemic.

To address the scientific obstacles and facilitate AIDS vaccine development, NIH continues to increase support for a broad program encompassing basic, preclinical, and clinical vaccine research on candidate vaccine products. As promising vaccines move further in the vaccine pipeline, expanded trials with populations at higher risk for HIV infection will become increasingly important. HIV/AIDS vaccine research requires trained health care, medical research, and prevention specialists from the populations at risk who will be integrally involved in development of vaccine candidates and clinical vaccine and prevention trials. International and domestic trial sites are being developed, including a cadre of trained indigenous or minority personnel, to conduct vaccine trials with the direct involvement of the communities at risk.

The development of an AIDS vaccine is a complex research challenge because HIV is unusually well-equipped to elude immune defenses, as exemplified by its ability to persist in almost all instances and eventually overcome the immune system. Many different vaccine approaches are being pursued. Initial studies are leading to more advanced vaccine candidates that may provide protection.

NIH has now conducted more than 50 Phase I and two Phase II clinical trials of nearly 30 vaccine products, individually or in combination, in human volunteers in collaboration with academic investigators and company co-sponsorship. Many of the early trials involved recombinant HIV envelope protein, the outer coating of the virus. However, complex vaccine products and products that contain other components of HIV have been included in a large number of these trials in the past few years. NIH has initiated the first vaccine trial in Africa.

To move forward in large-scale vaccine or prevention studies will require major efforts in communities that may be rarely involved in medical research. Development of infrastructure may need to be undertaken, as well as information dissemination and education of staff, potential participants, and community leaders of the groups that will participate in vaccine research.

Clearly, it will be more difficult to formulate an HIV/AIDS vaccine than was the case for prior vaccines directed against acute viral diseases. The scientific community must be mustered to make a broad and diverse attack upon this daunting challenge. Vaccine research is needed to attempt to unravel a wide variety of questions about the structure of the virus, its immunogenicity, the protective role of different components of the immune response, and the mechanism of viral escape from immune surveillance. In addition, fundamental work must be done to develop and refine a number of potentially effective methods for presentation of HIV antigens, including vectors engineered from a wide variety of viruses, and naked DNA itself. Building on this base, it will probably be important to utilize primate models to elucidate the mechanisms of protective immunity and to screen a multitude of candidate immunogens for the most promising products for clinical trials in humans.

RACIAL AND ETHNIC MINORITIES

Research Priorities of the FY 2002 Plan

- Recruit sufficient candidates to increase the pool of minority investigators for increased efficacy in HIV research.
- Decrease health disparities among racial and ethnic minorities with respect to HIV infection, as well as in comparison to majority populations.
- Promote the inclusion of racial and ethnic minorities in prevention, therapeutic, and clinical trials in numbers that are reflective of the incidence data.

NIH supports biomedical and behavioral research aimed at preventing, treating, and controlling HIV infection and its sequelae in minority communities. The disproportionate impact of the ongoing HIV/AIDS epidemic upon communities of color has presented significant challenges to biomedical, behavioral, social, and clinical research. The multifaceted nature of the epidemic in general, and specifically within racial and ethnic minority communities, requires a range of research interventions that target those components of the epidemic that facilitate, as well as limit, transmission. Within these communities, the impact of the main routes of HIV transmission in the United States—unprotected sexual intercourse and injecting drug use—are further confounded by other societal and community factors. These factors include poverty, homelessness, immigration, racism, violence, religion, social stigma, the sociocultural roles of women, the impact of acculturation, and homophobia.

NIH has for many years taken strong steps to assure minority participation in clinical trials, natural history and epidemiologic cohorts, and in prevention studies and to assure that the overall research agenda is responsive to the needs of minority communities. Minority participation in clinical trials must continue to keep pace with minority representation in the epidemic. For such participation to occur, research to identify the barriers to participation in clinical trials, as well as provider- and client-related barriers and needs, is essential.

NIH supports a broad array of behavioral intervention studies with specific focus on African American populations. These studies are characterizing the disease process in drug users, factors influencing disease progression, consequences of multiple co-infections, effectiveness of therapeutic regimens, and impact of health care access and adherence to therapeutic regimens on disease outcomes. The rising numbers of minority AIDS cases provide a powerful reminder that behavioral research must continue to define and utilize cultural, social, and contextual factors that affect HIV risk behavior. The role of alcohol and drug use in facilitating HIV transmission through social networks in all communities must also be explored within these social frameworks.

NIH has established programs and policies specifically designed to recruit individuals from underrepresented racial and ethnic groups into research careers and to build research infrastructure in

minority institutions. These programs provide training and research opportunities across the continuum from high school students to independent investigators. NIH also supports activities with the goal of disseminating research information to health care providers serving minority communities as well as directly to individuals at risk.

INTERNATIONAL AIDS RESEARCH

Research Priorities of the FY 2002 Plan

- Establish centers of excellence in international settings that will provide an environment that promotes the development of true and equal partnerships between U.S. and foreign investigators. These centers will support basic research and long-term cohort studies, serve as loci for studies of efficacy of biomedical and behavioral prevention interventions (including Phase I, II, and III vaccine trials), function as training centers for investigators from throughout the region, and serve as bridges in providing services.
- Conduct studies relevant to the geographic areas of the world and specific populations hardest hit by the epidemic.
- Enhance translation of research results into action that will improve patient management, develop prevention programs appropriate to the setting, and effect policy changes.
- Continue to enhance training for research needs, clinical capability, and technology transfer, building bridges with programs providing services where possible.

The exploding nature of the epidemic globally, particularly in the poorest parts of the world, has escalated the urgency of improved intervention strategies. For this reason, NIH has established the Global AIDS Research Initiative and will significantly increase its investments in international studies in the coming year. NIH supports a growing portfolio of research conducted in collaboration with investigators in developing countries. Results of this research benefit the people in the country where the research is conducted as well as people affected by HIV/AIDS worldwide. In addition, NIH supports an active program for training of researchers and health professionals from many countries.

For example, NIH collaborates with UNAIDS, host country governments, and in-country scientists in vaccine development and preparation for efficacy trials. Sites have been established in Uganda, South Africa, Haiti, Malawi, Thailand, India, Zimbabwe, Zambia, Trinidad and Tobago, Brazil, and Kenya. NIH-sponsored programs target studies on factors related to transmission of HIV and the pathogenic mechanisms associated with HIV disease progression through a number of studies in Africa, Asia, and Latin America. These studies focus on the biologic determinants of infectiousness and susceptibility.

It is critical to the success of international studies that foreign scientists be full and equal partners in the design and conduct of collaborative studies and that they have full responsibility for the conduct

of studies in-country. To that end, the NIH supports international training programs and initiatives that help to build infrastructure and laboratory capacity in developing countries where the research is conducted.

In recognition of the critical need to enhance NIH international research efforts, the OAR has established the Global AIDS Research Strategy Group. The Group is co-chaired by the Director of OAR and the Director of the National Institute of Allergy and Infectious Diseases, the institute with the largest international AIDS research portfolio. The Group provides a forum for discussion of current and planned international HIV research efforts; discussion of key scientific policy and bioethics issues in international research; and exchange of scientific information. The group includes representatives of the NIH institutes with major international AIDS research portfolios as well as other agencies, departments, and international organizations.

TRAINING AND INFRASTRUCTURE

Research Priorities of the FY 2002 Plan

- Continue to support training of domestic and international biomedical and behavioral AIDS researchers, including programs designed to recruit individuals from minority communities into research careers and to build research infrastructure in minority institutions.
- Continue to support improvement of facilities and equipment for the conduct of domestic and international AIDS research, including support of animal facilities for animal model research.

The NIH will continue to support training of domestic and international biomedical and behavioral AIDS researchers as well as the improvement of facilities and equipment for the conduct of AIDS research, including support of animal facilities for animal model research. Numerous NIH-funded programs have increased the number of training positions for AIDS-related research, including programs specifically designed to recruit individuals from minority communities into research careers and to build research infrastructure in minority institutions. The NIH Loan Repayment Program (LRP) was mandated by Congress under Public Law 100-607 in 1988 and authorized under 42 USC 288-1 to encourage health professionals to engage in AIDS-related research at the NIH. The Fogarty International Center sponsors the AIDS International Training and Research Program (AITRP), a program established in 1988 at the request of Congress to train scientists in developing countries to undertake AIDS research. The goal of the program is to expand scientific capabilities in the epidemiology, prevention, diagnosis, and treatment of HIV/AIDS throughout the world and to facilitate the evaluation internationally of AIDS interventions, such as vaccines and other strategies. The Regional Primate Research Centers (RPRC) Program, supported by the National Center for Research Resources, provides specialized facilities, scientific and technical personnel, animal models research and breeding, and a wide variety of non-human primate species to support diverse requirements for AIDS-related research.

INFORMATION DISSEMINATION

Research Priorities of the FY 2002 Plan

- Continue to support effective information dissemination approaches among researchers, health care providers, and affected communities to rapidly translate research into practice.

Effective information dissemination approaches will continue to be integral to HIV prevention and treatment efforts. Such programs are critical in light of the continuing advent of new and complex antiretroviral treatment regimens, the adherence issues related to HIV/AIDS treatment, the need for research communities to work and communicate globally, and the need to translate behavioral and social prevention approaches into practice. The changing pandemic and the increasing number of HIV infections in specific population groups, such as minorities and women, also underscore the need to disseminate HIV research findings and other related information to communities at risk. The flow of information among researchers, health care providers, and the affected communities represents new opportunities to rapidly translate research into practice and to shape future research directions.

NATIONAL INSTITUTES OF HEALTH

AIDS

SUMMARY BY MECHANISM

MECHANISM	FY 2000 Actual		FY 2001 Pre-recission Appropriation		FY 2001 Final Appropriation		FY 2002 Estimate	
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects								
Noncompeting	1,968	$759,909,000	2,096	$924,089,000	2,096	$924,089,000	2,256	$1,091,890,000
Administrative supplements	(132)	20,090,000	(86)	12,142,000	(86)	12,142,000	(74)	10,282,000
Competing:								
Renewal	210	148,391,000	236	128,390,000	236	128,390,000	240	123,025,000
New	550	228,011,000	608	240,472,000	608	240,472,000	589	228,092,000
Supplements	7	1,572,000	7	1,399,000	7	1,399,000	8	1,488,000
Subtotal, competing	767	377,974,000	851	370,261,000	851	370,261,000	837	352,605,000
Subtotal, RPGs	2,735	1,157,973,000	2,947	1,306,492,000	2,947	1,306,492,000	3,093	1,454,777,000
SBIR/STTR	99	26,971,000	112	31,010,000	112	31,010,000	127	35,312,000
Subtotal, RPGs	2,834	1,184,944,000	3,059	1,337,502,000	3,059	1,337,502,000	3,220	1,490,089,000
Research Centers								
Specialized/comprehensive	42	67,450,000	43	75,550,000	43	75,550,000	48	90,623,000
Clinical research	0	41,659,000	0	41,581,000	0	41,581,000	0	41,581,000
Biotechnology	0	4,939,000	0	6,819,000	0	6,819,000	0	6,892,000
Comparative medicine	7	33,070,000	13	39,146,000	13	39,146,000	13	46,342,000
Research Centers in Minority Institutions	0	7,888,000	0	8,476,000	0	8,476,000	0	8,876,000
Subtotal, Centers	49	155,006,000	56	171,572,000	56	171,572,000	61	194,314,000
Other Research								
Research careers	192	23,730,000	213	27,383,000	213	27,383,000	226	30,443,000
Cancer education	0	39,000	0	39,000	0	39,000	0	40,000
Cooperative clinical research	16	27,005,000	16	28,056,000	16	28,056,000	18	34,628,000
Biomedical research support	1	1,908,000	1	1,892,000	1	1,892,000	1	1,892,000
Minority biomedical research support	1	651,000	1	721,000	1	721,000	2	1,095,000
Other	91	32,471,000	59	35,422,000	59	35,422,000	60	38,738,000
Subtotal, Other Research	301	85,804,000	290	93,513,000	290	93,513,000	307	106,836,000
Total Research Grants	3,184	1,425,754,000	3,405	1,602,587,000	3,405	1,602,587,000	3,588	1,791,239,000
Training	FTTPs		FTTPs		FTTPs		FTTPs	
Individual awards	74	2,503,000	76	2,798,000	76	2,798,000	78	3,124,000
Institutional awards	745	26,306,000	766	28,941,000	766	28,941,000	784	31,718,000
Total, Training	819	28,809,000	842	31,739,000	842	31,739,000	862	34,842,000
Research & development contracts	153	204,237,000	170	234,166,000	170	233,641,000	195	267,945,000
(SBIR/STTR)	(3)	(893,000)	(2)	(850,000)	(2)	(850,000)	(3)	(1,250,000)
Intramural research		230,765,000		248,307,000		248,226,000		266,561,000
Research management and support		65,147,000		73,891,000		73,413,000		80,548,000
Cancer prevention & control		0		0		0		0
Construction		0		0		0		0
Library of Medicine		5,063,000		5,525,000		5,525,000		6,677,000
Office of the Director		44,653,000		48,271,000		48,234,000		53,540,000
Subtotal		2,004,428,000		2,244,486,000		2,243,365,000		2,501,352,000
Buildings and Facilities		0		0		0		0
Total, NIH		2,004,428,000		2,244,486,000		2,243,365,000		2,501,352,000
(Clinical Trials)		(397,116,000)		(447,864,000)		(447,864,000)		(497,556,000)

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

Spending by the HIV-Related Research Plan
(dollars in thousands)

Research Area	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	Change
Natural History and Epidemiology	$238,604	$262,135	$282,974	$20,839
Etiology and Pathogenesis	582,682	642,270	701,318	59,048
Therapeutics	570,401	629,211	673,324	44,113
Vaccines	232,107	281,734	356,589	74,855
Behavioral and Social Science	275,185	310,673	357,105	46,432
Training and Infrastructure	76,463	84,999	95,097	10,098
Information Dissemination	28,986	32,343	34,945	2,602
Total, Budget Authority	2,004,428	2,243,365	2,501,352	257,987

National Institutes of Health

Office of AIDS Research

AIDS Funding by Institute and Center

Institute/Center	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate
NCI	$230,474,000	$237,860,000	$251,200,000
NHLBI	65,527,000	68,008,000	71,717,000
NIDCR	20,193,000	21,862,000	22,937,000
NIDDK	21,983,000	24,562,000	27,360,000
NINDS	33,621,000	37,674,000	42,264,000
NIAID	928,695,000	1,062,592,000	1,192,855,000
NIGMS	37,128,000	43,298,000	47,891,000
NICHD	89,540,000	101,666,000	114,496,000
NEI	10,890,000	11,555,000	12,730,000
NIEHS	7,541,000	7,769,000	8,166,000
NIA	3,919,000	4,386,000	4,985,000
NIAMS	5,022,000	5,629,000	6,404,000
NIDCD	1,590,000	1,592,000	1,596,000
NIMH	128,562,000	145,051,000	161,417,000
NIDA	217,898,000	244,902,000	284,741,000
NIAAA	19,218,000	21,195,000	24,402,000
NINR	7,501,000	9,663,000	10,978,000
NHGRI	4,188,000	5,750,000	6,158,000
NIBIB	---	---	---
NCRR	105,788,000	117,410,000	129,112,000
NCCAM	1,030,000	1,030,000	1,630,000
NCMHD	---	---	---
FIC	14,404,000	16,152,000	18,096,000
NLM	5,063,000	5,525,000	6,677,000
OD	44,653,000	48,234,000	53,540,000
B&F	---	---	---
TOTAL, Bud. Auth.	2,004,428,000	2,243,365,000	2,501,352,000

NATIONAL INSTITUTES OF HEALTH
Office of AIDS Research

SIGNIFICANT ITEMS IN HOUSE AND CONFERENCE
APPROPRIATIONS COMMITTEE REPORTS

FY 2001 House Appropriations Committee Report Language (H. Rpt. 106-645)

Item

[AIDS allocation]-- The Committee intends that the funds allocated for AIDS should be spent in a manner fully consistent with the AIDS research plan developed by the Office of AIDS Research (OAR) and expects the Director of NIH to use the full authority of his office to ensure that this occurs. The Committee has provided the Director of OAR, jointly with the Director of NIH, transfer authority to reallocate up to three percent of funds designated for AIDS research among Institutes, subject to normal reprogramming procedures. The Committee encourages NIH to use this authority whenever it believes that an adjustment in the allocation of AIDS funding between Institutes is appropriate to achieve scientific objectives or to facilitate promising research efforts. (p. 57)

Action taken or to be taken

The Director of OAR, in consultation with the Director of NIH, allocated all monies for AIDS-related research to the Institutes and Centers in accordance with the scientific priorities and objectives of the NIH FY 2001 Plan for HIV-Related Research. OAR develops an annual comprehensive AIDS research plan and budget, based on the most compelling scientific priorities that will lead to better therapies and prevention for HIV infection and AIDS. Those priorities are determined through a unique and collaborative process involving the NIH institutes and non-government experts from academia and industry, with the full participation of AIDS community representatives. The plan is divided into five Scientific Areas of Emphasis and four Areas of Special Interest. *Scientific Areas of Emphasis* include: Natural History and Epidemiology; Etiology and Pathogenesis; Therapeutics; Vaccines; and Behavioral and Social Science. *Areas of Special Interest,* which cross-cut all of the scientific areas, include: Racial and Ethnic Minorities; International Research Priorities; Training, Infrastructure, and Capacity Building; and Information Dissemination. The Plan serves as the framework for developing the NIH AIDS budget, for determining the use of NIH AIDS-designated dollars, and for tracking and monitoring those expenditures.

The OAR appreciates the critical flexibility that the 3% transfer authority provides to move funds to meet the scientific priorities. Because the opportunity existed to make changes in the distribution of funds to the Institutes and Centers at the time of the conference committee, we do not anticipate the need to utilize the 3% transfer at this time. We will reserve the use of this critical authority for only the most pressing need that could not be addressed by use of the OAR Discretionary Fund, for example, if a scientific breakthrough required expanded clinical trials.

Item

Office of AIDS Research – ...The Committee expects the Director of NIH to use this plan and the budget developed by OAR to guide his decisions on the allocation of AIDS funding among the Institutes. The Director of NIH also should use the full authority of his office to ensure that the ICDs spend their AIDS research dollars in a manner consistent with the plan. In addition, the OAR allocates an emergency AIDS discretionary fund to support research that was not anticipated when the budget allocations were made. (p. 93)

Action taken or to be taken

The Director of OAR in consultation with the Director of NIH has allocated all monies for AIDS-related research to the Institutes and Centers in accordance with the scientific priorities and objectives of the NIH FY 2001 Plan for HIV-Related Research. The Plan serves as the framework for developing the NIH AIDS budget as well as for determining the use of NIH AIDS-designated dollars. In addition, all AIDS-designated expenditures are coded and tracked in accordance with the objectives and priorities of the plan.

FY 2001 Conference Appropriations Committee Report Language (H. Rpt. 106-1033)

Item

[HIV/AIDS in people of color] – The agreement includes funds within the Office of the Director to address the trend of the HIV/AIDS epidemic in communities of color. The Office is encouraged to expand and strengthen science-based HIV prevention research for Africans Americans, Latinos, Native Americans, Asian Americans, Native Hawaiians and Pacific Islanders and consideration should be given to the U.S. Virgin Islands and Puerto Rico. The Office is also encouraged to expand existing culturally competent behavioral research, conducted by minority principal investigators, that seeks to break the link between HIV infection and high risk behaviors and that seeks to decrease the rate of mortality in targeted minority populations. (p. 141)

Action taken or to be taken

NIH AIDS Research Priorities

Research to address the disproportionate impact of the HIV/AIDS epidemic on U.S. racial and ethnic minority communities continues to be a high priority of the Office of AIDS Research. OAR established the Ad Hoc Working Group on Minority Research to advise us on the scientific priorities in this critical research area. OAR is directing increased resources toward new interventions that will have the greatest impact on these groups. These include interventions that address the co-occurrence of other STDs, hepatitis, drug abuse, and mental illness; and interventions that consider the role of culture, family, and other social factors in the transmission and prevention of these disorders in minority communities. Specific prevention research priorities also include vaccine development; microbicides

and other female-controlled interventions; behavioral intervention; interruption of perinatal transmission; immune reconstitution; and simpler and less expensive antiretroviral treatment regimens. These strategies focus on the salient problems confronting African American and other minority populations, as well as the medically indigent, homeless, and drug-using groups. The key priorities are prevention of transmission; prevention of disease progression; and prevention of mortality.

OAR has provided additional funds to projects aimed at: increasing the number of minority investigators conducting behavioral and clinical research; targeting the links between substance abuse, sexual behaviors and HIV infection; increasing outreach education programs targeting minority physicians and at-risk populations; and expanding our portfolio of population-based research.

Training and Career Development Workshops
One of these projects is the Training and Career Development Workshop series for racial and ethnic minority investigators. These workshops are designed to: 1) increase awareness of the types of NIH funding available for HIV/AIDS research, especially in Prevention and Treatment; 2) provide protected time to meet and discuss with senior minority scientists research projects to be conducted in racial and ethnic minority communities, and to seek technical advice and assistance, 3) review in detail the steps involved in submission of research applications to the National Institutes of Health and the types of mechanisms available for funding, and 4) interact with NIH program staff from a variety of Institutes with specific research initiatives and/or interests that target racial and ethnic minority communities.

Research Infrastructure Development
The OAR recently collaborated with the National Institute of Neurological Diseases and Stroke (NINDS) in the solicitation of another Specialized Neurosciences Research Program (SNRPs) site. These sites represent a unique partnership between majority and minority institutions, in which collaboration is essential to tackle some of the major complications of HIV infection in the human central nervous system. Several of these centers have developed into free standing Centers of Excellence that have become magnets for other minority investigators from trainees to senior scientists.

Computer Access Initiative
The OAR recently launched a program to provide computer hardware and software to scientists at minority predominant and minority serving institutions to assist in the development of research infrastructure, access to national databases for further investigation of time trends in racial and ethnic minorities, and to facilitate the development of research networks of these institutions.

Regional Technology Transfer Programs
OAR established this program in 1990 to encourage underserved and disadvantaged communities to solicit support from OAR for workshops for individuals and groups that provide health care services to people infected with HIV/AIDS. These workshops deliver new information about progress and ongoing programs in HIV/AIDS research so health care providers will have the most current and useful information available to them in their treatment of patients.

Five of these workshops have been held in conjunction with the Continuing Medical Education Center

of the University of Puerto Rico on various topics of diagnosis and management of HIV infection, and another is in the planning stages for outreach to Spanish-speaking populations in the Carribean. Four workshops have been sponsored in conjunction with the Indian Health Service on topics regarding clinical management of HIV infection in Native American communities; and another is planned for January 2002 with satellite links to the Alaska Native healthcare region. Four workshops were sponsored in collaboration with the NIH Office of Research on Women's Health on topics of Women and HIV. One of these was with Meharry Medical College; and another with the U.S. Virgin Islands Department of Health.

In February, 2000 OAR sponsored a meeting entitled "Heightening Awareness of HIV/AIDS in the Caribbean Region: Bridging the Gap from Denial to Acceptance to Prevention -- Preparing for the Next Millennium." The OAR developed this conference with the encouragement and support of Dr. Donna Christian-Christensen, the U.S. Congressional Representative for the U.S. Virgin Islands, and with the assistance of health care professionals and community representatives. To accommodate the greatest number of participants across the Caribbean, the OAR worked with the Ministries of Health for Barbados, Trinidad and Tobago, Jamaica, and the Bahamas and invited their regional participation in this 2-day workshop.

Representatives from St. Thomas, St. Croix, Barbados, Trinidad and Tobago, Jamaica and the Bahamas, worked collaboratively to develop morning plenary sessions that were broadcast by satellite from St. Thomas to each of the four additional islands. The groups on each island held afternoon sessions on topics of more local and targeted interest. These topics ranged from prenatal care and prevention of perinatal transmission to cultural considerations in prevention, treatment, and care. More than 2,300 participants attended, including health care professionals and community representatives. To expand the audience beyond those who were able to attend, the plenary sessions and many of the afternoon sessions from the various islands were videotaped and can now be viewed on the OAR Web site.

OAR has also partnered with the National Minority AIDS Council to support a series of regional meetings to bring research results and their treatment applications to community-based organizations across the U.S.

Item

[HIV prevention] **--** The conferees are concerned about the transfer of HIV prevention interventions that have proven to be effective to service programs supported by other Federal agencies, such as CDC and HRSA. The Office of AIDS Research (OAR) should work with the ICs to increase NIH efforts in this area through the establishment of programs for regional technical assistance, technology transfer, and training for the purpose of providing links between evidence-based HIV prevention science and public health departments, community planning groups, healthcare providers, and prevention service providers. (p. 142)

Action taken or to be taken

The OAR supports Regional Technology Transfer Meetings and other workshops and conferences, in conjunction with other federal agencies, such as HRSA, IHS and VA that focus on integrating effective HIV prevention interventions into clinical care and other health service settings. For example, the OAR recently co-sponsored a large meeting with the VA to bring NIH-supported HIV prevention researchers together with providers and consumers in the VA health care system to determine how best to integrate effective prevention interventions into the VA HIV, substance use, women's health, and addiction treatment programs for veterans and their families. Prevention researchers are providing continuing technical assistance to the VA service providers in regularly scheduled conference calls. In addition, the OAR is co-sponsoring another in a series of HIV/AIDS conferences with the Indian Health Service that will provide state-of the-art technology transfer information in HIV/AIDS prevention and care for providers who work in the Indian Health Service/Tribal/Urban health care systems and affiliated entities that work closely with American Indian/Alaska Native communities. OAR is also sponsoring a Regional Technology Transfer conference focusing on Asian Pacific Island populations.

Item

[Review of five year plan] -- The conferees commend the Office of AIDS Research for convening an external review of the Centers for AIDS Research Program and for the five year plan to increase the number of Centers. However, the conferees urge the NIH to consider ways in which the five year plan can be modified to balance the need to expand the number of Centers with the need to adequately support the leading AIDS research institutions with the core center mechanisms that they need to efficiently pursue AIDS research. (p. 142/143)

Action taken or to be taken

The Office of AIDS Research is committed to a strong and efficient CFAR program. Further, it is our goal that funds allocated to this program serve the best interest of AIDS researchers at those sites. After consideration of the pressing research needs and available resources, we are committed to expanding the number of sites as well as supporting existing sites with supplemental funding on a case-by-case basis for new and expanded research initiatives.